Incyte Announces Data for Pemigatinib, its Selective FGFR Inhibitor, to be Featured at the ESMO 2018 Congress

October 9, 2018

Interim Phase 2 results highlight the potential of pemigatinib (INCB54828) in cholangiocarcinoma and urothelial carcinoma

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 9, 2018-- Incyte (Nasdaq:INCY) announces that interim Phase 2 data on its investigational, selective FGFR1/2/3 inhibitor, pemigatinib (INCB54828), will be presented at the upcoming European Society for Medical Oncology (ESMO) 2018 Congress taking place in Munich, Germany from October 19-23, 2018.

Data at ESMO 2018 will include poster presentations on the FIGHT-202 study of pemigatinib in patients with previously treated advanced/metastatic or surgically unresectable cholangiocarcinoma (bile duct cancer) with fibroblast growth factor (FGF)/FGFR genetic alterations, as well as the FIGHT-201 study of pemigatinib in patients with metastatic or surgically unresectable urothelial carcinoma (bladder cancer) harboring FGF/FGFR genetic alterations.

"We are pleased that data on pemigatinib – part of our targeted therapy portfolio – have been selected for presentation at this year's ESMO Congress," stated Steven Stein, M.D., Chief Medical Officer, Incyte. "We look forward to sharing updated interim data from the ongoing FIGHT-202 trial of pemigatinib in patients with cholangiocarcinoma, which continue to support our plan for a 2019 NDA submission in this indication, as well as updated data from the FIGHT-201 study of pemigatinib in patients with urothelial carcinoma, which support recruitment into the continuous dosing cohort of this study."

Abstracts were made available today on the ESMO Congress website at https://www.esmo.org/Conferences/ESMO-2018-Congress.

Poster details:

Interim Results of FIGHT-202, a Phase 2, Open-Label, Multicenter Study of INCB054828 in Patients (pts) with Previously Treated Advanced/Metastatic or Surgically Unresectable Cholangiocarcinoma (CCA) with/without Fibroblast Growth Factor (FGF)/FGF Receptor (FGFR) Genetic Alterations *(Abstract #756P, poster display session)*

- Sunday, 21 October 2018 from 12:45 p.m. CEST to 1:45 p.m. CEST (6:45 a.m. ET to 7:45 a.m. ET) in Hall A3 – Poster Area Networking Hub

Interim Results of FIGHT-201, a Phase 2, Open-Label, Multicenter Study of INCB054828 in Patients (pts) with Metastatic or Surgically Unresectable Urothelial Carcinoma (UC) Harboring Fibroblast Growth Factor (FGF)/FGF receptor (FGFR) Genetic Alterations (GA) *(Abstract #900P, poster display session)*

- Monday, 22 October 2018 from 12:45 p.m. CEST to 1:45 p.m. CEST (6:45 a.m. ET to 7:45 a.m. ET) in Hall A3 – Poster Area Networking Hub

Full session details and data presentation listings for ESMO 2018 can be found at: https://cslide.ctimeetingtech.com/esmo2018/attendee/.

About FGFR and Pemigatinib (INCB54828)

Fibroblast growth factor receptors (FGFRs) play an important role in tumor cell proliferation and survival, migration and angiogenesis (the formation of new blood vessels). Activating mutations, translocations and gene amplifications in FGFRs are closely correlated with the development of various cancers.

Pemigatinib is a potent, selective, oral inhibitor of FGFR isoforms 1, 2 and 3 which, in preclinical studies, has demonstrated selective pharmacologic activity against cancer cells with FGFR alterations. Phase 2 studies investigating the safety and efficacy of pemigatinib monotherapy across several FGFR-driven malignancies are ongoing—the FIGHT (FIbroblast Growth factor receptor in oncology and Hematology Trials) clinical trial program currently comprises FIGHT-201 in patients with metastatic or surgically unresectable bladder cancer, including with activating FGFR3 alterations; FIGHT-202 in patients with metastatic or surgically unresectable cholangiocarcinoma who have failed previous therapy, including with activating FGFR2 translocations; and FIGHT-203 in patients with myeloproliferative neoplasms with activating FGFR1 translocations.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company's website at www.incyte.com.

Follow @Incyte on Twitter at https://twitter.com/Incyte.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the presentation of data from the Company's ongoing clinical development program for pemigatinib and its potential in treating cholangiocarcinoma and urothelial carcinoma and the Company's plans to file an NDA for pemigatinib and the expected timing of such filing, contain predictions, estimates and other forward-

looking statements.

These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; determinations made by the FDA; the Company's dependence on its relationships with its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; greater than expected expenses; expenses relating to litigation or strategic activities; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended June 30, 2018. The Company disclaims any intent or obligation to update these forward-looking statements.

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